

**REMARKS**

In the Office Action dated October 14, 2008, the Examiner:

- a) made final the election of species presented in Office Action of October 30, 2007, and further withdrew claim 9 from consideration;
- b) objected to the Abstract;
- c) suggested guidelines for headings in the Specification;
- d) objected to claims 2 and 7 for informalities;
- e) rejected claims 1-7 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite; and
- f) rejected claims 1, 4, 7, 8, 11-15, 17, and 18 under 35 U.S.C. § 102(b), as being anticipated by Moller (US 2002/0052578).

Applicant traverses restrictions, objections and rejections for the following reasons.

**ELECTION/ RESTRICTIONS**

In the Office Action dated October 14, 2008, the Examiner made final the Restriction/Election Requirement dated October 30, 2007, and withdrew claims 5, 6, 9, 10 and 16 from further consideration.

In its Response to the Restriction/ Election Requirement of November 30, 2007, Applicant submitted that claims 5, 6, 10, and 16 are drawn to a non-elected species. However, claim 9 was not in the listing of withdrawn claims and Applicant traverses the withdrawal of claim 9 for at least the following reason.

The Examiner alleges that “the rigid keying of the portions of the dose dial sleeve together...is a characteristic of non-elected Species II.” Office Action, page 3.

However, the feature, “rigid keying of the portions of the dose dial sleeve together” depicted in Fig. 6 of non-elected Species II is the same as the engaging feature between portions of dose dial sleeve depicted in Figs. 1-5 and thus reads on Figs. 1-5. Therefore, the Applicant respectfully submits that claim 9 reads on elected Species I and should be considered on its merits with elected claims 1-4, 7, 8, 11-15, 17, and 18.

#### **OBJECTION TO THE ABSTRACT**

Applicant has deleted the Abstract and provided a Replacement Abstract in proper U.S. format. Accordingly, Applicant respectfully requests withdrawal of the objection to the Abstract.

#### **AMENDMENTS TO THE SPECIFICATION**

Applicant acknowledges the Examiner’s suggested guidelines for formatting the Specification. Accordingly, Applicant has amended the Specification to insert headings corresponding to the suggested guidelines as appropriate.

### **OBJECTION TO CLAIMS**

Applicant has amended claim 2 to clarify the claim language. With regard to claim 7, Applicant respectfully requests reconsideration. Applicant submits that it is proper to state that “the insert and an inner surface of the first section include” the recited features, rather than “including” as proposed by the Examiner. Accordingly, Applicant respectfully requests withdrawal of the objection to claims 2 and 7.

### **CLAIM REJECTIONS**

Applicant has amended claims 1, 2, and 8, and cancelled non-elected claims 19-21 without prejudice or disclaimer. Applicant reserves the right to present these claims in a related application. The originally-filed specification, claims, and the replacement abstract, and drawings fully support the amendments. Applicant also has added new claim 22. New claim 22 is supported by the originally-filed specification and drawings, e.g., paragraphs [0066] and [0073] and Figs. 1-5. Thus this Reply to Office Action introduces no new matter. Claims 1-18 and 22 are pending, with claims 5, 6, 10 and 16 being withdrawn from consideration as drawn to a non-elected species.

#### **35 U.S.C. § 112 Rejection:**

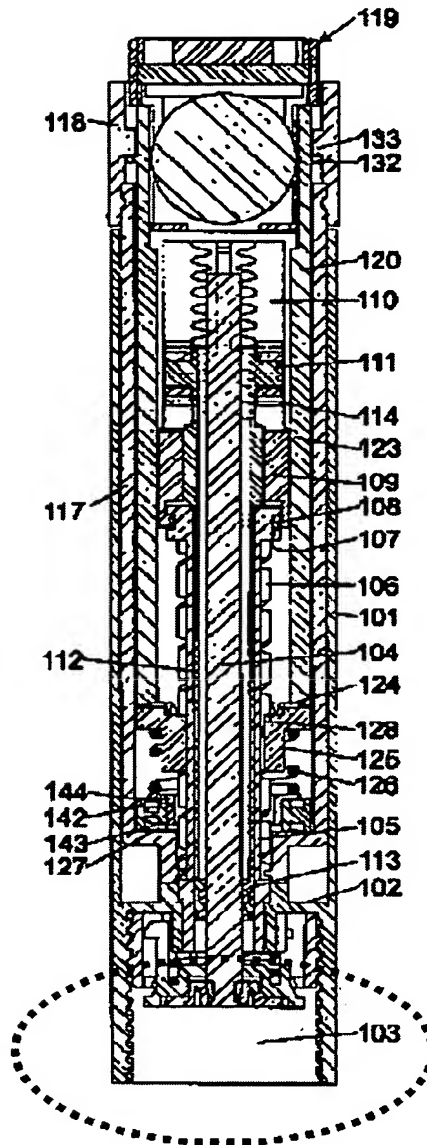
The Examiner rejected claim 8 under 35 U.S.C. § 112, 2nd paragraph. Applicant has amended claim 8 to clarify the claim language. Withdrawal of this rejection is respectfully requested.

#### **35 U.S.C. § 102(b) Rejection:**

In the Office Action, claims 1- 4, 7, 8, 11-15, 17, and 18 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Moller (US 2002/0052578) (“Moller”).

In order to properly establish that Moller anticipates Applicant's claims under 35 U.S.C. § 102, each and every element as set forth in the claims must be found, either expressly or inherently described, in a single prior art reference. M.P.E.P. § 2131., 8th Ed., Rev. 7 (July, 2008). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989)).

With regard to claim 1, Moller fails to disclose or suggest, among other things, a "unitary housing" and a "cartridge . . . enclosed within the housing together with [a] dose selecting means and [a] dose expelling means," as recited in amended claim 1. The Examiner asserts that Moller discloses, *inter alia*, a dose selecting means (dose setting drum 17 or 117) and a dose expelling means (tubular element 20 or 120) and a unitary housing 1 or 101 with which the dose selecting means and the dose expelling means are retained. Office Action, pp. 6-7. Moller, however, does not disclose a "cartridge . . . enclosed within the housing together with [a] dose selecting means and [a] dose expelling means." Instead, Moller discloses a cartridge that is detachable from the housing, and not contained within the housing as claimed. For example, as shown in the figure below, drawings on sheet 3 (not numbered) of Moller depict a threaded part of a compartment 103 through which a cartridge (not shown) is coupled to the compartment 103. This cartridge is not enclosed within the housing with the tubular element 120 and the dose setting drum 117.



(reproduced from sheet 3 of Moller (not numbered); dotted line added)

Accordingly, Applicant submits that the above-discussed feature for claim 1 is not disclosed or suggested by Moller. For at least the above reason, Applicant submits that independent claim 1 is allowable over Moller. Accordingly, Applicant requests the allowance of independent claim 1.

With regard to claim 2, Moller fails to disclose, among other things, "ratchet means associated with the insert to ensure the piston rod only rotates in a single

direction through the insert,” as recited in claim 2. Fig. 1 of Moller illustrates a system that includes nut 13 on the piston rod 32 engaged with the insert. The Examiner asserts that the nut 13 of Moller corresponds to ratchet means of the present application. Office Action, page 7. However, in the discussion of the nut 13 of Fig. 1 of Moller, the following comments are made:

The rotation of the gearbox 25 is through the connection bars 12 transmitted to the nut 13, which is this way screwed up along the thread of the piston rod 4 and lifted away from its abutment with the wall 2 when a dose i[s] set. As the dose is set by moving the nut 13 on the very piston rod which operates the piston in the not shown ampoule in the compartment 3 a dose setting limiter, which ensures that the size of the set does not exceed the amount of medicament left in the ampoule, can easily be established by providing the piston rod 4 with a stop 35 which limits the movement of the nut 13 up along the piston rod 4.

(Page 3, paragraph [0030] of Moller).

Claim 2 requires that the “ratchet means associated with the insert...ensure[s] [that] the piston rod only rotates in a single direction through the insert.” Moller discloses that the nut 13 can move up and down along the thread of the piston rod 4 and thus allows the bidirectional rotation of the piston rod 4 relative to the nut 13. At least for this reason, Applicant submits that Moller does not disclose or suggest all of the features of claim 2 and thus cannot anticipate claim 2.

For at least the above reason, Applicant submits that independent claim 2 is allowable over Moller. Accordingly, Applicant requests the allowance of independent claim 2, and for at least the same reasons, the allowance of claims 3, 4, 7-9, 11-15, 17 that depend from claim 2. Further, upon allowance of claim 2, Applicant respectfully requests rejoinder and reconsideration of non-elected claims 5, 6, 10, and 16, which depend from claim 2.

Finally, to the extent that the rejection of claims 1 and 2 is applicable to new claim 22, Applicant provides the following comments. New claim 22 requires, in part, "a dose expelling means that directly engages an end of [a] piston rod." Moller does not disclose or suggest at least this feature. For at least the above reason, Applicant submits that new claim 22 is allowable over Moller. Accordingly, Applicant requests the allowance of claim 22.

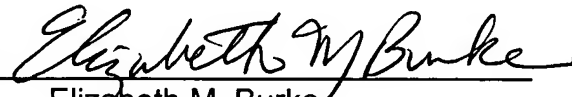
In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application, and timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: February 17, 2009

By:   
Elizabeth M. Burke  
Reg. No. 38,758  
(202) 408-4000

**Attachment : Replacement Abstract**